510(k) SUMMARY
(as required by 807.92(c))

OCT - 7 2011

Regulatory Correspondent:
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Submitter of 510(k):
CardioComm Solutions Inc.
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Victoria, BC, V8T 3J5
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Date of Summary: September 9, 2011

Trade/Proprietary Name: GlobalCardio

Classification Name: Medical magnetic tape recorder (21 CFR 870.2800, Product Code DSH)

Common Name: Health monitoring data management device

Intended Use:
GlobalCardio is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. GlobalCardio includes a QRS Algorithm that will analyze the 12 Lead ECG and produce measurements of the ECG recording as well as textual interpretation.

GlobalCardio will be accessed over the Internet and data will be stored at either the client site or at the central GlobalCardio data warehouse. Data will be secure, and with separate data stores for each client. Users will be able to access specific modules for managing patient cardiac related data such as arrhythmia data that fit their patients' needs. GlobalCardio is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GlobalCardio does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Device Description:
GlobalCardio is a cardiology software product, delivered over the web using the Application Service Provider (ASP) model. GlobalCardio operates on IBM compatible PCs and runs within an Internet browser, Microsoft Internet Explorer. GlobalCardio operates as a client server application. GlobalCardio presents an interface for health care professionals to input, store, query and output data from a centrally hosted, or client based relational database.

The product is a web-based database system for the secure storage of all aspects of a patient's cardiology record including: arrhythmia follow-up and diagnosis, trans-telephonic pacemaker follow-up, implantable cardioverter defibrillator (ICD) follow-up, in-clinic follow-up, 12 Lead ECG testing, cardiac rehabilitation data, stress test data pathological diagnosis, ECGs, ECG information, clinical history, physician notes, clinical history and associated reports and queries.

GlobalCardio is a comprehensive ECG management system. GlobalCardio is sold in two ways:

- Per-use or fee-for-service. Software is not shipped and installed, but instead customer accounts are set up for access and record management from the centrally hosted web application. Login IDs and passwords are created for each authorized client. Databases reside in the secure, firewall protected, warehouse at the application host site.
- Technology licensing. GlobalCardio technology is licensed to another company which then hosts a complete service, as described above, including secure data warehousing.

All activity on GlobalCardio is recorded by User ID. User IDs are provided for each customer to access their own secure database(s).

GlobalCardio is designed as a multi-user system capable of supporting large volumes of simultaneous users.

Data can be entered via keyboard, mouse, bar code reader, sound card, serial port, or IrDA port, and stored to and retrieved from any computer media. Information can be displayed on the computer monitor or printed.

GlobalCardio is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

The purpose of this submission is to include the 12 Lead ECG and Digital Device Integration modules.

Predicate Device: GlobalCardio (K013354)
CardioView 32 Review Module (K083321)

Substantial Equivalence:
The proposed device is substantial equivalent to the GlobalCardio (K033037) device. The proposed device has t similar intended use technological, and design characteristics as the predicate devices. Any minor differences do not introduce new issues of safety or effectiveness.

Performance Testing:
Verification and validation activities related to the device modification were performed on the applicant device, and the predetermined acceptance criteria were met in all cases. The activities included scenario validations, report viewing and customization testing, algorithm confirmation testing, and device functional testing.

Conclusion:

The results of the non-clinical performance testing and device comparison demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CardioComm Solutions, Inc.
c/o Mr. Jon Ward
AJW Technology Consultants Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

OCT - 7 2011

Re: [510(k)] K111320
Trade/Device Name: GlobalCardio
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH, DPS
Dated: September 13, 2011
Received: September 13, 2011

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111320

Device Name: GlobalCardio

GlobalCardio is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. GlobalCardio includes a QRS Algorithm that will analyze the 12 Lead ECG and produce measurements of the ECG recording as well as textual interpretation.

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Prescription Use: X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111320